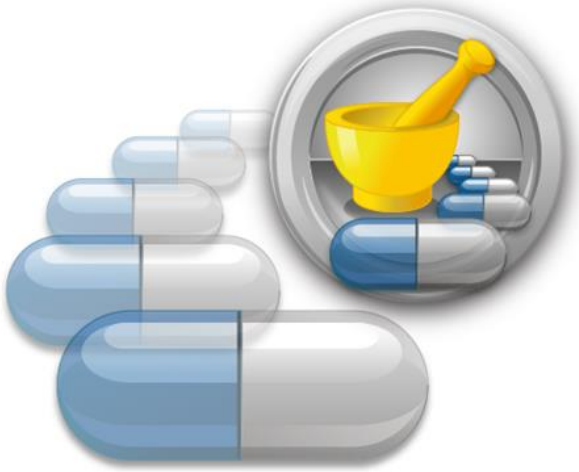
FactoryTalk PharmaSuite 11.01.00

Quality Certificate



This document has been reviewed and approved electronically via Rockwell's Document Management System [1].
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Period of Validity

This document is valid for the release on the cover page – FactoryTalk PharmaSuite 11.01.00.

Introduction

PharmaSuite® is a suite of software applications that is tailored to the needs of the Pharmaceutical and Biotech manufacturing industry. Special regulations are in place for these industries, and many of them also apply to software that is used during the course of production of a drug product or medical device. Therefore, the software has to be developed under consideration of the pertinent regulations and related requirements. In addition, appropriate validation of the deployed software system has to be performed before it can be used in the production environment.

PharmaSuite® is developed under consideration of all pertinent regulations that are relevant for its use in the Pharmaceutical and Biotech manufacturing industry. This is particularly true for the features of the software itself, but also for the process how the software is developed, which is based on a mature Quality Management System. Moreover, PharmaSuite® includes extensive technical, functional, and quality documentation. With that, PharmaSuite® includes all prerequisites required for a successful deployment and validation at customer's site.

Quality Certificate

This Quality Certificate provides evidence that the activities that were planned and subsequently executed to design, develop, and test FactoryTalk PharmaSuite 11.01.00 have been successfully completed according to the principles defined in the MES Quality Management System (QMS) [2]. Product- and project-specific adaptations have been described in the Project Plan [7] and the Test Plan [8] for FactoryTalk PharmaSuite 11.01.00.

The Quality Document [12] provides a more detailed elaboration of quality-related activities performed for this release. Customers can obtain the Quality Document on request. In addition to that, Rockwell Automation provides customers access to the complete quality documentation of every release during an official audit.

FactoryTalk PharmaSuite 11.01.00 underwent extensive tests for several test types. Testing results have been summarized in the Test Summary Report [9]. All completed test cases and their result are listed in the Final Test Status Report that has been generated out of the test management tool [10]. All acceptance criteria of the single tests of the different test types are fulfilled as described in the Testing Guideline [6] and as mandated by the underlying MES QMS [2]. This Quality Certificate certifies that these tests have successfully demonstrated the functional correctness of FactoryTalk PharmaSuite 11.01.00 in all GxP-relevant aspects.

All deviations have been managed according to the change control procedures and guidelines ([3], [4], and [5]) in the deviation management system. Deviations relevant for customers have been documented in the Release Notes [11].

The formal approval of the Project Closure Report [13] officially closed the project.

The system has been qualified and is ready for release.

In case of changes applied to FactoryTalk PharmaSuite 11.01.00, additional testing may be limited to changed or enhanced parts only. For all unchanged parts, the release documentation of FactoryTalk PharmaSuite 11.01.00 may be referenced, provided appropriate change control mechanisms are being applied.

Released Product Information

Product Name / Version	Release Build Number[1]
FactoryTalk PharmaSuite 11.01.00	11.01.00.09

FactoryTalk PharmaSuite 11.01.00 is an extension of FactoryTalk PharmaSuite 11.01.00. It is backward compatible except for the changes listed in the Release Notes [11].

[1] For individual build numbers of phases released in conjunction with FactoryTalk PharmaSuite 11.01.00, please refer to the *FTPS 11.01.00 – Building Blocks – Compatibility Matrix* [14] which also documents compatibility between PharmaSuite and building block versions.

Test Scope Statement

Functionality provided by the underlying software,

- FactoryTalk ProductionCentre 11.02.01.006
- and various commercial (COTS) and open source software (OSS) components used,

has generally not been tested explicitly (unless otherwise mentioned), but implicitly through the functionality tested for FactoryTalk PharmaSuite 11.01.00.

As an example, the JGraph library listed as one of several 3rd party components used within FactoryTalk PharmaSuite 11.01.00 (see Tool Overview and Assessment [15]) is used to draw the graphical layouts of S88 master recipes and master workflows, thereby supporting the recipe and workflow authors. Many test cases have been specified and executed to verify the correctness of inserting new elements, moving or replacing elements etc.

Another example is the usage of ProductionCentre functionality. Working with activity sets is implicitly tested by generating and executing production orders or workflows out of S88 master recipes or master workflows, whereas user and user group management is explicitly tested, as these functions are used 1:1 in FactoryTalk PharmaSuite 11.01.00.

References

Copyright of all reference documents by Rockwell Automation:

[1] Rockwell Automation Document Management System (DMS), basic functionality included in central SAP

[2] MES Binding Work Instructions (100-01)

[3] Anomaly Management Process (BSRC-5515)

[4] Processing of Anomalies (107-07)

[5] Processing of Stories (108-01)

[6] Risk-Based Testing Guideline (105-07)

[7] FTPS 11.01.00 – Project Plan

[8] FTPS 11.01.00 – Test Plan

[9] FTPS 11.01.00 – Test Summary Report

[10] FTPS 11.01.00 – Final Test Status Report

[11] FTPS 11.01.00 – Release Notes

[12] FTPS 11.01.00 – Quality Document

[13] FTPS 11.01.00 – Project Closure Report

[14] FTPS 11.01.00 – Building Blocks – Compatibility Matrix

[15] FTPS 11.01.00 - Tool Overview and Assessment

Note: For DIR numbers and latest revisions of the FTPS 11.01.00-specific documents, refer to “FTPS 11.01.00 - Documents and Approvals”, DIR 10007172713/REV.

Revision History and Approvals

Revision History

The following table describes the history of this document. Each version has been approved per Document Management System [1].

Version	Author	Description
1.0	Gaurav Bindal	Initial version created.

Approvals

Approvals are captured electronically on the organization's Document Management System [1]. The required approvers of this document include the following:

Role	Name
Product Manager	Andreas Grossmann
Engineering Manager	Steffen Landes
Quality Manager	Eva Mueller